Betelcare Sdn Bhd (120426-A)

Lot 3342, Jalan Keretapi Lama, 7½ Mile, Off Jalan Kapar,
42200 Kapar, Selangor Darul Ehsan, West Malaysia.

Tel: (603) 3290 3301, (603) 3290 3302
Fax: (603) 3290 3303
Email: betel@pd.jaring.my
www.betel.com.my

510K Summary for BETELCARE SDN BHD-Latex Exam gloves Blue Powder Free

K073299

MAR - 5 2008

1. Submission Applicant:

   Name: Betelcare Sdn Bhd
   Address : Lot 3342,Jalan Keretapi Lama
   7.5 Miles Off Jalan Kapar,Kapar
   Selangor Darul Ehsan
   West Malaysia
   Telephone No: 603 3290 3301 Fax No: 603 3290 3303
   Email address : kbsiah@betel.com.my
   Contact Person: K.B .Siah

   Registration Form 2891 number: 8040910
   Device Listing Number : A 653345
   Activity : Manufacturer

   Applicant 510k number: K893166,C047750

2. Device Particulars:
   Device Name : Powder Free Latex Exam gloves Blue
   Common Name : Chlorinated Blue Powder Free Latex Exam Gloves
   Classification: Patient Examination Gloves

3. Device Classification
   Device Class: Class II Product code: LYY

4. Device Classification
   Device Class: Class II Product code: LYY

5. Summary of Intended Use
   A medical gloves is worn on the hand of healthcare and or similar personnel to prevent contamination between healthcare personnel and the patient.

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6. Comparison Characteristic:

Characteristic	Reference Doc	Betel Device performance
Water Leak	ASTM D 5151-06	Meets or Exceeds
Residue Powder	ASTM D6124-06	Meets or Exceeds
Unaged	ASTM D 3578-05	Meets or Exceeds
Tensile :-Aged	ASTM D 3578 -05	Meets or Exceeds
Unaged	ASTM D 3578-05	Meets or Exceeds
Elongation@break		
Unaged	ASTM D 3578-05	Meets or Exceeds
Aged	ASTM D 3578 -05	Meets or Exceeds
Extractable Protein Test	ASTM D 5712-05e1	Meets or Excceds

The above device does NOT include "hypoallergenic'labelling in packing.

7. Labeling and Attributes
   Safe use of this gloves by or on latex sensitized individuals has not been established.This product contains natural rubber latex which may cause allergic reactions in some individual.

8. Assesment of Non clinical Performance Data
   The device meets or exceeds the ASTM Std or Equivalent Standards and FDA pin hole requirements

9. Assesment of Biocompatibility

   Primary Skin Irritant Test: Pass
   Dermal Sensitization Study: Pass

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10. Conclusion of non clinical and biocompability performance

The device has been carefully compared to legally marketed devices in the 510K.The data summaries indicates that the proposed device meets or exceeds all acceptable requirements for Powder Free Latex Exam gloves blue non sterile

I,Keng Beng Siah,the Chief Executive Officer of BETELCARE SDN BHD,certify That to the best of my knowledge and belief and based on the data and Information submitted to me in the course of my responsibilities as CEO of Betelcare Sdn Bhd and in reliance thereupon the data and information Submitted in the pre market notification are truthful and accurate no facts Materials to a review of the substantial equivalence of the device have been Knowingly omitted from this submission.

	KENG BENG SIAH	22nd Feb 2008
Signature	Name	Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 2008

Mr. Keng Beng Siah
Director
Betelcare Sdn Bhd
Lot 3342 Jalan Keretapi Lama
7 1/2 Mile, Off Jalan Kapar, 42200 Kapar
Selangor Darul Ehsan,
WEST MALAYSIA

Re: K073299
Trade/Device Name: Betel Latex Exam Gloves, Blue, Powder Free, Non Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: February 22, 2008
Received: February 27, 2008

Dear Mr. Siah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

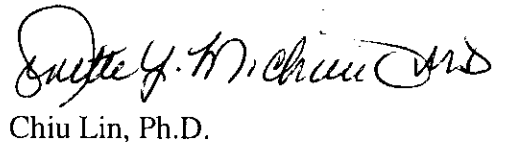
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 510K number is K073299

Device Name: Betel Latex Exam Gloves,Blue ,powder Free,Non sterile

Indications For Use:

A patient examination gloves is a disposable device intended for medical purposes worm on the examiner,s hand to prevent contamination between patient and examiner.

This gloves is intended for medical and dental use.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073299